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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,517	09/22/2003	Andre Stamm	107664.115 US12	5828
26694	7590	11/02/2005	EXAMINER	
VENABLE LLP			SHEIKH, HUMERA N	
P.O. BOX 34385			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20045-9998			1615	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,517

Applicant(s)

STAMM ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/22/03; 6/18/04; 6/28/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Power of Attorney (POA) Notice filed 09/30/05 and the Information Disclosure Statements (IDS) filed 09/22/03, 06/18/04 and 06/28/04 is acknowledged.

Claims 1-56 are pending in this action. Claims 1-56 are rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application Nos. 10/665,516; 10/665,518; 10/665,519 and 10/665,522.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims of the 10/665,517 application and the each of the above-cited copending applications claim similar subject matter. For example, the instant claims are

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drawn to a composition comprising fenofibrate and at least one pharmaceutical excipient, wherein the composition has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate. The claims of the copending applications listed above also recite fenofibrate compositions, in various forms, including tablets, capsules and suspensions comprising excipients and polymers. Thus, the compositions recited in the claims of the copending applications listed above are directly within the scope of the compositions of the instant claims. The copending application claims are directly within the scope of the instant pending claims, thereby creating an 'anticipation situation' in obvious type double patenting.

Additional properties claimed are inherent by the use of the particular drug, fenofibrate in combination with excipients known in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

There are numerous applications that may necessitate a double patenting rejection due to the breadth of the claims, as can be seen by an inventors name search of US Patents and Applications. It would constitute an undue burden for the Examiner to specifically analyze each of the numerous patent applications. A quick search turned up the copending applications above that appear to have similar subject matter as claimed. The Examiner requests a complete list of

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both patents and pending applications, which may initiate a double patenting rejection because of the undue burden presented by the numerous overlapping subject matter with the instant claims.

This is a provisional obviousness-type double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent Nos. 6,652,881; 6,589,552; 6,596,317; 6,277,405; 6,074,670; Patent Application Publication US2002/0009496 A1 (09/899,026) and Patent Application Publication US2003/0104060 A1 (10/290,333). Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant claims of the 10/665,517 application and each of the above-cited U.S. Patents/Patent Application Publications.

For example, the instant claims are drawn to a composition comprising fenofibrate and at least one pharmaceutical excipient, wherein the composition has a dissolution of at least 10% in

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5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate. The claims of the above-cited U.S. Patents/Patent Application Publications also recite fenofibrate compositions, in various forms, including tablets, capsules and suspensions comprising excipients and polymers. Thus, the compositions recited in the claims of the U.S. Patents/Patent Application Publications listed above are directly within the scope of the compositions of the instant claims. The U.S. Patents/Patent Application Publications claims are directly within the scope of the instant pending claims, thereby creating an 'anticipation situation' in obvious type double patenting.

Additional properties claimed are inherent by the use of the particular drug, fenofibrate in combination with excipients known in the art.

There are numerous applications that may necessitate a double patenting rejection due to the breadth of the claims, as can be seen by an inventors name search of US Patents and Applications. It would constitute an undue burden for the Examiner to specifically analyze each of the numerous patent applications. A quick search turned up the U.S. Patents/Patent Application Publications above that appear to have similar subject matter as claimed. The Examiner requests a complete list of both patents and pending applications, which may initiate a double patenting rejection because of the undue burden presented by the numerous overlapping subject matter with the instant claims.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh



Patent Examiner

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October 27, 2005